K072330

BIOMET BIOLOGICS, INC.

510(k) Summary

November 30, 2007

DEC 06 2007

Applicant/Sponsor: Biomet Biologics, Inc.

Contact Person: Paula Deming, RN, BSN

Proprietary Name: Curved Delivery Option (CDO™ System) & Graft Preparation System

Common Name: Piston Syringe

Classification Name: FMF (21 CRF 880.5860)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

CDO™ System

K030208 IMBIBE II Syringe (Orthovia, Inc., Malvern, PA)

K022246 Symphony Graft Delivery System (DePuy AcroMed, Raynham, MA)

Graft Preparation System

K021071 Graft Delivery System (Biomet Biologics, Inc., Warsaw, IN)

Device Description:

CDO™ System

The CDO™ System consists of a curved delivery cannula, a modified syringe, a flexible plunger and an optional syringe adaptor tip.

Graft Preparation System

The Graft Preparation System consists of a modified syringe with a check valve, plunger, nozzle cap and end cap.

Indications for Use:

CDO™ System

The CDO™ System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft material with I.V. fluids, blood, plasma concentrate, platelet-rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

Graft Preparation System

The Graft Preparation System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft material with I.V. fluids, blood, plasma concentrate, platelet-rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

Summary of Technologies: The overall designs, materials and processing methods are similar to the predicate devices to which substantial equivalence is claimed for both the CDO™ and Graft Preparation Systems.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the devices were functional within their intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2007

Biomet Biologics, Inc.
% Paula Deming
Regulatory Specialist
PO Box 587
Warsaw, Indiana 46581

Re: K072330
Trade/Device Name: Curved Delivery Option (CDO™) and Graft Preparation System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 30, 2007
Received: December 03, 2007

Dear Ms. Paula Deming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072330

Device Name: Curved Delivery Option (CDO™ System) and Graft Preparation System

Indications For Use:

CDO™ System

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Graft Preparation System

The Graft Preparation System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft material with I.V. fluids, blood, plasma concentrate, platelet-rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buell

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072330